REMARKS

I RESTRICTION REQUIREMENT AND PROVISIONAL ELECTION

The Examiner imposed a restriction requirement on pending claims 1-76 which were divided into Groups I-VI as follows; Group I, claims 1-10, drawn to methods of modulating the transport of leptin across the blood-brain barrier; Group II, claims 11-22, drawn to methods of modulating body weight; Group III, claims 23-32, drawn to methods of modulating appetite; Group IV, claims 33-39, drawn pharmaceutical compositions; Group V, claims 40-56, 58, drawn to the use of compounds for the manufacture of medicaments for modulating the transport of leptin across the blood-brain barrier; and, Group VI, claims 57, 59-76 drawn to the use of compounds for the manufacture of medicaments fro modulating the body weight of an animal.

In response to the restriction, the Applicant **elects Group I** (claims 1-10), with traverse.

The Examiner has also issued two election of species requirements, designated in Group A, agents that modulate leptin transport across the blood-brain barrier, and Group B, leptins.

In response to the Group A election, Applicant **elects agent (a) epinephrine**, claims 5, 16, 27 34 41 and 58.

In response to the Group B election, Applicant **elects leptin (b)**, SEQ ID NO: 4, claims 3, 4, 13, 14, 25, 26, 33, 56, and 73. Traversal of this election is presented below.

Applicants reserve the right to request rejoinder of the species and the non-elected claims upon allowance of the generic claims.

II THE SUBJECT MATTER OF THE ELECTED CLAIMS

The subject matter of the claims in general relates to methods of modulating the transport of leptin across the blood-brain barrier, and methods related to that transport such as modulating body weight and modulating appetite in a mammal.

III. TRAVERSAL OF RESTRICTION TO GROUPS I-VI

The present application is a U.S. National Phase Application of PCT Application No. PCT/US00/23110 and as such the contention that there are multiple inventions claimed in the application under 35 U.S.C. 121 is subject to a lack of unity requirement according to 35 U.S.C. 372. In order for there to be proper unity of invention, the invention must be directed to a single inventive concept comprising a common technical relationship among the inventions characterized by the presence of a common technical feature. The common technical feature is defined as meaning those attributes which define the contribution which each claimed invention, considered as a whole, makes over the art. Applicants submit that all of the claims in the present application share a common technical feature.

The claims of the present invention are all directed to methods of modulating leptin transport in order to modulate body weight, or appetite in a mammalian subject. The specification describes that modulation of leptin transport is a means for modulating body weight or appetite. For example, leptin transport across the blood brain barrier (BBB) may be increased, thereby reducing body weight and decrease in appetite. Conversely, leptin transport across the BBB may be decreased resulting in an increase in appetite or body weight (page 3, line 28, to page 4, line 8). Thus, each claim in the invention shares the common technical feature of modulation of leptin transport across the BBB.

Because they share a common technical feature, the claims of the present invention

do not place an undue burden on the Examiner to search the invention. A search in the relevant databases will encompass all the functions of leptin taught in the prior art, including methods for administration of leptins to treat mammalian conditions. Thus, a restriction is improper as there is no evidence of serious burden on the Examiner to search the invention.

In addition to the above, Applicant submits that the present rejection is improper based on International Application No. PCT/US/00/23110, of which the present application is a U.S. national phase application. The International Search Report (ISR) issued in the PCT application recorded a lack of unity objection. However, the ISR segregates the claims based only on the compound administered to the mammalian subject. This unity objection is similar to the restriction made to the election of species in Group A.

Applicant submits that, even if it were determined that there is a serious burden in searching the claimed invention, the restriction requirement should be formulated such that the claims herein should be treated similarly to those in the PCT application under the unity of invention restriction (PCT Rule 13.1). The Unity of Invention objection in the related PCT application was not directed to each method disclosed in the application as the present restriction is, e.g., method of modulating leptin transport, body weight, or appetite, but is strictly based on the compound administered. Additionally, the unity of invention in the PCT application did not suggest an election of species to a specific leptin composition. The restriction issued in the present application goes beyond that in the PCT application, despite the supposed similar treatment of the claims. As such, the restriction made in the present application is improper.

IV. TRAVERSAL OF RESTRICTION TO A SINGLE SPECIES IN GROUP B

Applicant submits that the requirement for election of species of Group B is improper. Election of species is required when the species are deemed to lack unity of invention

because they are not so linked as to form a single general inventive concept.

Applicant submits that the Group B species form a general inventive concept, as the species are all leptin molecules having the biological function of leptin taught throughout the specification. The specification teaches that leptin molecules, include leptin variants, analogs, fragments, consensus leptons, or derivatives, which have the ability to modulate weight or to alter metabolism is useful in the invention (page 9, lines 11-13). The specification discloses that preferred leptin compounds include SEQ ID NO: 2, SEQ ID NO: 5, SEQ ID NO: 4, SEQ ID NO: 6, variants and analogs thereof (page 9, lines 4-20). The specification further describes how to make analogs, fusion proteins, and N-terminally modified variants of the leptin molecules. These molecules share a common technical feature of biological activity of leptin.

Moreover, SEQ ID NOs: 4 and 6 are both native human leptin molecules, SEQ ID NO: 4 defines the leptin molecule comprising a signal peptide while SEQ ID NO: 6 is the mature leptin protein. Similarly SEQ ID NOs: 2 and 5 comprise native murine leptin, SEQ ID NO: 2 comprising the signal peptide at the N-terminus, while SEQ ID NO: 5 is the mature protein. These molecules also share a common technical feature of biological activity of leptin.

A search of leptin proteins based on any one of the sequences set out above will predictably produce the remainder of the proteins set out above, as well as leptin fragments, variants, consensus sequences, and fusion proteins. As such, it does not place an undue burden on the Examiner to search all of the leptin molecules designated in Group B since they are essentially the same molecule, and a search of one leptin molecule would produce the additional leptin molecules.

Applicant submits that the "species" of group B comprise a single technical feature

and are improperly subject to restriction under the unity of invention practice.

V. CONCLUSION

No fees are believed due in connection with the filing of this response, however, should any fees be deemed necessary, the Commissioner is hereby authorized to deduct any such fees from Marshall, Gerstein and Borun LLP account number 13-2855.

Respectfully submitted,

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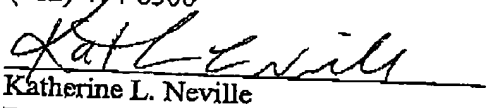
By: 

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